REMARKS

The Office Action of 6/24/03 has been carefully reviewed. For the reasons set forth in detail below, reconsideration and withdrawal of each of the rejections is hereby courteously requested.

Claims 2- 17, 19, 21, 22 and 25 - 34 are pending in the Application.

Claims 5, 7 and 14 - 16 are finally rejected under U.S.C. §102 (b) as being anticipated by Anderson 4197842. The rejection is traversed for the reasons stated below.

The Examiner asserts that; "the system (of Anderson), is fully capable for use in response to symptoms of an attack of a vascular disease." Applicant agrees that the system of Anderson teaches a device that provides breathable oxygen to a user. Applicant has further stipulated that the administration of breathable oxygen provides a benefit to a person suffering from an attack of a vascular disease. Oxygen breathed by a person in trauma increases oxygen saturation in the blood. The increased oxygenation decreases the possibility of tissue damage from infarction during an ischemic event caused by an obstruction of blood circulation. During or immediately after a heart attack, stroke or an attack from any other arterial illness or condition that causes a local obstruction of blood circulation, any oxygen breathed by the victim can reduce permanent tissue damage and may prevent death. (See Applicants specification on page 1, line 30 - page 2, line 8.) However, applicant's present invention is not just a device that provides breathable oxygen to areas affected by a blood flow restriction.

Applicant's claims 5 - 7 set out the specific limitation of; a breathable oxygen delivery system and a medication for use in response to symptoms of an attack of a vascular disease. Applicant's specification specifically details two separate treatments for heart attack and stroke. The first and foremost being the administration of breathable oxygen; and, the second being the administration of a medication or agent affecting thrombus formation or blood clotting, e.g. anticoagulants or antiplatelets, which inhibit platelet aggregation. (See Applicants specification on page 12, line 17 - page 13, line 6. Other second treatment examples given by Applicant include the administration of cardioprotective agents, e.g. Beta Blockers, antiarrythmics, e.g. magnesium and other

vasocative agents, e.g. ACE inhibitors. Still further second treatment examples include medications that induce arteriolar relaxation, e.g. nitroglycerin and a medication that reduces the need for oxygen.

Applicant's claims 14 - 16 include the specific limitations of: a breathable oxygen delivery system and a medication for one of; assisting in preventing thrombosis; assisting in inducing arteriolar relaxation; assisting in establishing a cardiac rhythm; and, assisting in diminishing oxygen demand. The system of Anderson provides none of these medications and is completely silent regarding any treatment of a vascular disease, or regarding the use of breathable oxygen as a treatment for heart attack or stroke.
The Examiner is reminded that; "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference." *Verdgaal Bros. v Inion Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)

Anderson neither expressly nor inherently describes any medication or agent for treating a vascular disease, for assisting in preventing thrombosis; for assisting in inducing arteriolar relaxation; for assisting in establishing a cardiac rhythm; or for assisting in diminishing oxygen demand as required by Applicant's claims 5, 7 and 14 - 16. Moreover, Anderson never expressly describes a specific medication. However, Anderson does expressly state (Abstract, line 1): "The invention provides a pulmonary respirator used in the treatment of such diseases as Pulmonary Emphysema, Asthma, Bronchitis and other respiratory diseases in addition to supplying emergency pure oxygen to the heart and airways of the patient." (Emphasis added). Although Anderson expressly states that pure oxygen is supplied to the heart he is completely silent about any use of the device to treat heart attack or vascular disease.

Applicant respectfully submits that the Anderson reference does not anticipate Applicant's claims 5, 7 and 14 - 16, because it fails to expressly or inherently teaches each and every element set forth therein. Specifically, Anderson fails to teach agents affecting thrombus formation or blood clotting, cardioprotective agents, antiarrythmics, medications that induce arteriolar relaxation or medications that decrease the need for

oxygen. Withdrawal of the rejection of claims 5, 7 and 14 - 16 under 35 U.S.C. §102 (b) as being anticipated by Anderson, is hereby requested.

Claims 2 - 4, 13, 17, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Monhan 4699288. The rejection is traversed for the reasons stated below.

As stated above, Anderson neither expressly nor inherently teaches any of the second treatments of applicant's claims, namely, any medication, in addition to oxygen, for use in response to symptoms of an attack of a vascular disease. Each of claims 2 - 4, 13, 26 and 27, requires this limitation. Similarly, Anderson neither expressly nor inherently teaches a medication for assisting in preventing thrombosis; assisting in inducing arteriolar relaxation; assisting in establishing a cardiac rhythm; or assisting in diminishing oxygen demand. Claim 17 requires this limitation. Applicant can find no suggestion by Anderson to combine the pulmonary respirator, described therein, with any medication except for a medication used in the treatment of such diseases as Pulmonary Emphysema, Asthma, Bronchitis and other respiratory diseases. Moreover, Anderson is completely silent regarding use of the device taught therein for treating heart attack, stroke or any vascular disease. Accordingly, Anderson never teaches or suggests the specific limitations of claims 2 - 4, 13, 17, 26 and 27.

Mohan teaches a high-pressure vessel or tank constructed to resist fragmentation, e.g. when struck by a bullet. Mohan suggests that the vessel provides sufficient structural strength for containing high-pressure fluids, (Col. 3, line 47). However, Mohan never teaches or suggests a medication for use in response to symptoms of an attack of a vascular disease, as required by claims 2 - 4, 13, 26 and 27. Likewise, Mohan never teaches or suggests a medication for one of; assisting in preventing thrombosis; assisting in inducing arteriolar relaxation; assisting in establishing a cardiac rhythm; and, assisting in diminishing oxygen demand as required by Applicant's claim 17. Accordingly, Mohan never teaches or suggests the specific limitations of claims 2 - 4, 13, 17, 26 and 27.

The Examiner is reminded that: "To establish *prima facie* obviousness of a claimed invention all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 891, 180 USPQ 580 (CCPA 1974).

Since neither Anderson or Mohan alone nor Anderson and Mohan in combination teach or suggest all of the claimed limitations, specifically, neither reference teaches or suggests agents affecting thrombus formation or blood clotting, cardioprotective agents, antiarrythmics, medications that induce arteriolar relaxation or medications that decrease the need for oxygen, Applicant respectfully submits that the Examiner has failed to establish a case of *prima facie* obviousness. Accordingly, reconsideration and withdrawal of the rejection of claims 2 - 4, 13, 17, 26 and 27 under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Monhan 4699288 is hereby requested.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Lowell et al. 6292687. The rejection is traversed for the reasons stated below. Applicant can find no suggestion by Anderson to combine the pulmonary respirator, described therein, with any medication except for a medication used in the treatment of such diseases as Pulmonary Emphysema, Asthma, Bronchitis and other respiratory diseases. Moreover, Anderson is completely silent regarding is of the device taught therein for treating heart attack, stroke or any vascular disease. Accordingly, Anderson never teaches or suggests the specific limitations of claim 6, which requires a medication for use in response to symptoms of an attack of a vascular disease.

Lowell et al. describe a heart dysfunction reader that detects a heart dysfunction occurrence. Lowell et al. also teach combining the heart dysfunction reader with an alarm for indicating that a heart dysfunction has occurred. Lowell et al. further teach a system for locating the user and for locating an Automatic External Defibrillator (AED), local to the heart dysfunction reader, for treating a heart dysfunction by defibrillation. However, Lowell et al. fail to teach or suggest a breathable oxygen supply and a medication for use in response to symptoms of an attack of a vascular disease.

Since neither Anderson or Lowell et al. alone, nor Anderson and Lowell et al. in combination, teach or suggest all of the claimed limitations, specifically, neither reference

teaches or suggests agents affecting thrombus formation or blood clotting, cardioprotective agents, antiarrythmics, medications that induce arteriolar relaxation or medications that decrease the need for oxygen, Applicant respectfully submits that the Examiner has failed to establish a case of *prima facie* obviousness. Accordingly, reconsideration and withdrawal of the rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Lowell et al. 6292687 is hereby requested.

Claims 8-10, 11 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Zapol et al. 6063407. The rejection is traversed for the reasons stated below.

As stated above, Applicant can find no suggestion by Anderson to combine the pulmonary respirator, described therein, with any medication except for a medication used in the treatment of such diseases as Pulmonary Emphysema, Asthma, Bronchitis and other respiratory diseases. Although Anderson expressly states that pure oxygen is supplied to the heart he is completely silent about any use of the device to treat heart attack or vascular disease. Applicant's claims 8, 31 and 32 require a medication, (in addition to breathable oxygen), for use in response to symptoms of an attack of a vascular disease, specifically, agents affecting thrombus formation or blood clotting cardioprotective agents, antiarrythmics, medications that induce arteriolar relaxation or medications that decrease the need for oxygen. Accordingly, Anderson fails to teach or suggest the limitations of Applicant's claims 8, 31 and 32. Similarly, Applicant's claims 9 and 30 specifically require an anticoagulant and claim 10 and 29 specifically require a cardioprotective agent, which are not taught or suggested by Anderson. Accordingly, Anderson also fails to teach or suggest the limitations of Applicant's claims 8-10, 11 and 29 - 32.

Zapol et al. teach methods of treating, inhibiting or preventing vascular diseases, e.g. vascular thrombosis and or arterial restenosis resulting from excessive intimal hyperplasia, (Col. 1, lines 12-16). Each of the methods taught by Zapol et al. requires that a therapeutically effective amount of gaseous nitric oxide, (NO) be inhaled by the mammal being treated, (Col. 1, line 60 - Col. 2 line 4, Col. 4, line 46 and line 63, Col. 5,

line 42, Col. 6, lines 13 - Col. 7 line 15). According to Zapol et al., inhaled NO acts as an antithrombotic agent. Zapol et al. further teach combining other antithrombotic agents with inhaled NO, "so that their separate antithrombotic activity is advantageously used to augment the antithrombotic effect(s) of inhaled NO", (Col. 8, line 35).

Applicant can find no suggestion by Zapol et al. to administer breathable oxygen to increase oxygen saturation in the blood thereby reducing the risk that infarction that may result from vascular disease and or arterial restenosis. Moreover, Zapol et al. are completely silent regarding heart attack or stroke. Regarding oxygen, Zapol et al. explicitly states; "It is vital that the NO be obtained and stored as a mixture free of any contaminating O_2 or higher oxides of nitrogen, because such higher oxides of nitrogen (which can form by reaction of O_2 with NO) are potentially harmful to lung tissue." (Col. 6, line 19-24). Zapol et al. also teach that NO may be administered at a concentration of from 0.1 ppm to 300 ppm in air, pure oxygen, or another suitable gas or gas mixture, for as long as needed." (Col. 6, line 63.) Although Zapol et al. suggests mixing NO with pure oxygen, they never suggest that pure oxygen serves any other purpose than to provide a mixing gas for diluting the NO. Specifically, Zapol et al. never suggest that using pure oxygen as a mixing gas, instead of air or another suitable gas, offers any benefit or difference in treating, inhibiting or preventing vascular diseases, e.g. vascular thrombosis and or arterial restenosis resulting from excessive intimal hyperplasia. In fact, upon reading Zapol et al. one of ordinary skill might select air as the preferred mixing gas given the dangers of mixing contaminating O_2 with NO, as reported therein.

Zapol et al. teach treating, inhibiting or preventing vascular diseases using antithrombotic agents exclusively, with the exception that Zapol et al. also teach administering phosphodieterase inhibitors in conjunction with NO to enhance the affects of the NO. (col. 7, lines 39 - 59). However, Zapol et al. make absolutely no suggestion that a breathable oxygen supply for increasing oxygen saturation in the blood might be used in combination with the antithrombotic agents, (including inhaled NO), to provide the benefit of reducing the risk of infarction caused by reduced blood circulation. Applicant's claims 8, 31 and 32 require a breathable oxygen delivery system and a

medication for use in response to symptoms of an attack of a vascular disease. Similarly, Applicant's claims 9 and 30 require a breathable oxygen delivery system and an anticoagulant, while claim 10 and 29 require a breathable oxygen delivery system and a cardioprotective agent.

Although Anderson teaches a breathable oxygen supply and Zapol et al. teach medications for use in response to symptoms of an attack of a vascular disease, there is no suggestion in either reference to combine their teachings. Applicants have already admitted that it was known at the time of the present invention to provide breathable oxygen alone in response to symptoms of an attack of a vascular disease, especially heart attack and stroke, to increase oxygen saturation in the blood. Likewise, Applicant has already admitted that it was known at the time of the present invention to treat an attack of a vascular disease with prescription and non-prescription medications such as nitroglycerin for providing arteriolar relaxation and aspirin to reduce blood clotting, respectively. The Examiner is reminded that:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Millis, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)

Neither Anderson nor Zapol et al. suggest the desirability of combining breathable oxygen with a medication responsive to symptoms of an attack of a vascular disease. Neither Anderson nor Zapol et al. suggest the desirability of combining breathable oxygen with an anticoagulant or a cardioprotective agent. These limitations are required by Applicant's claims 8-10, 11 and 29-32. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness because the prior art fails to suggest the desirability of the combination. Reconsideration and withdrawal of the rejection of claims 8-10, 11 and 29-32 under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Zapol et al. 6292687 is hereby requested.

The Examiner states that; "Zapol et al. teaches the use of inhaled medication to prevent thrombosis." Applicant respectfully submits that the teaching by Zapol et al. to inhale the antithrombotic agent NO is insufficient to suggest that the patient inhale

oxygen, to increase oxygen saturation in the blood to reduce the risk of infarction in areas affected by reduced blood flow, which results from a heart attack, stroke or any other vascular trauma.

Claims 12, 28, 29, 33 and 34 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Anderson in view of Duhaylongsod 6141589.

As stated above, Anderson fails to teach or suggest medications for use in response to symptoms of an attack of a vascular disease and specifically never teaches or suggests an antiarrythmic agent as required by claim 28 or magnesium as required by claim 12. Anderson also fails to teach or suggest a medication provided in a dosage capable of establishing a cardiac rhythm as required by claim 33 or capable of diminishing oxygen demand as required by claim 34.

Duhaylongsod teaches techniques for stopping the heart from beating during surgery using an atriovetricular (AV) node blocker in combination with a β-blocker administered in an amount sufficient to reduce the amount of AV node-blocker to induce ventricular asystole. (Col. 5, lines 37 - 46.) Duhaylongsod states that when the heart is stopped, blood flow to the rest of the body is provided via a cardiopulmonary bypass, (CPB) and deoxygenated blood is infused with oxygen. (See Col. 1, lines 38 -50). Duhaylongsod teaches that cardioplegic agents such as a mixture of magnesium sulfate, potassium citrate and neostigmine induce cardioplegia during CPB.

As stated in Applicant's earlier response, regarding Duhaylongsod, the entire teaching is directed to surgical procedures and use of various compounds during cardiac, neuro and vascular surgery that require precise control of cardiac contraction for stopping the heart from beating. Again, Applicant respectfully submits that a teaching of medications used in sufficient amounts for stopping the heart from beating during surgery does not suggest or even suggest a desirability that such medications be used in the emergency medical kit of Applicant's invention to establish a cardiac rhythm. The Examiner is reminded that:

"The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)

Applicant submits that neither Anderson or Duhaylongsod alone, nor Anderson and Duhaylongsod in combination, teach or suggest the claimed combination of rejected claims 12, 28, 29, 33 and 34. Claims 33 and 34 require a breathable oxygen supply and a medication in a dosage capable of establishing a cardiac rhythm or a medication in a dosage capable of diminishing oxygen demand, included in an emergency medical kit. Neither of the references cited teach nor suggest this combination and neither of the references suggest that the combination would have a reasonable expectation of success. In fact, both references are completely silent regarding a medication capable of diminishing oxygen demand. Claims 12 and 28 require a breathable oxygen supply and an antiarrythmic agent, e.g. magnesium, included in an emergency medical kit. Neither of the references cited teach nor suggest this combination and neither of the references suggest that the combination would have a reasonable expectation of success.

The Examiner asserts that Duhaylongsod teaches a common inhalable antiarrythmic agent comprising magnesium for controlling the heart and that it would have been obvious to one of ordinary skill in the art to include the antiarrythmic of Duhaylongsod, (in an emergency medical kit), for precise pacing and control of cardiac contraction during a heart attack or surgery. For the reasons stated above, Applicant respectfully disagrees. Duhaylongsod teaches stopping the heart to provide a substantially motionless operative field. Duhaylongsod describes maintaining the ability of the heart to be electrically paced but never does Duhaylongsod suggest precisely pacing or controlling the heart during a heart attack by proper administration of an antiarrythmic agent as alleged by the Examiner. Accordingly, Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness because the prior art fails to teach or suggest the claimed combination and because the prior art lacks any suggestion that the claimed combination has a reasonable expectation of success. Reconsideration and withdrawal of the rejection of claims 12, 28, 29, 33 and

34 under 35 U.S.C. 103 (a) as being unpatentable over Anderson in view of Duhaylongsod is hereby requested.

Claims 19, 21, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zapol et al. in view of Kirchgoerg et al. 6327497.

As stated above, Zapol et al. teach treating, inhibiting or preventing vascular diseases using antithrombotic agents exclusively, with the exception that Zapol et al. also teach administering phosphodieterase inhibitors in conjunction with NO to enhance the affects of the NO. (col. 7, lines 39 - 59). However, Zapol et al. make absolutely no suggestion that a breathable oxygen supply for increasing oxygen saturation in the blood might be used in combination with the antithrombotic agents, (including inhaled NO), to provide the benefit of reducing the risk of infarction caused by reduced blood circulation. Every treatment taught by Zapol et al. requires administration of therapeutically effective amount of inhaled gaseous nitric oxide, (NO), which they claim acts as an antithrombotic agent. Zapol et al. is completely silent regarding increasing oxygen saturation in the blood when a person is in trauma and makes no suggestion to administer breathable oxygen, other than as a mixing gas for delivering NO. Accordingly, Zapol et al. never teach or suggest the specific limitations of claims 19, 21, 22 and 25, which each require providing a breathable oxygen delivery system to a person with known susceptibility to an attack of a vascular disease.

The Examiner states that Zapol et al. teach the steps of establishing a risk and predetermining a treatment. Applicant submits that every treatment taught by Zapol et al. includes inhaled NO and that Zapol et al. never suggests any treatment other than administering antithrombotic agents. The Examiner further points to (col. 4, lines 46-50) to suggest that Zapol et al. teach the step of teaching the patient how to recognize the symptoms of the serious attack. Applicant disagrees with this characterization by the Examiner. The referenced citation explicitly states; "Mammals and humans in particular, are known to display various signs and symptoms of a thrombosis and may be identified thereby. The recognition of such symptoms is within the skill <u>of medical practitioners</u>.' (Emphasis added) Applicant submits that Zapol et al. does not teach or suggest the step

of teaching the patient how to recognize the symptoms of the serious attack and how to carry out the treatment, as required by Applicants claim 19, 21 and 25.
The Examiner points to (col. 6, lines 56-59) in support that Zapol et al. teach providing a patient with a portable emergency medical kit, however, the cited reference refers to providing an inhaler of NO combined with a phosphodieterase inhibitor that may prolong the beneficial effects of the NO gas. Applicant submits that this teaching fails to suggest or to suggest the desirability of an emergency medical kit that includes breathable oxygen and a medication such as those as required by each of claims 19, 21, 22 and 25.

Kirchgeorg et al. teaches an electronic emergency medical system including a breathable oxygen delivery system, an Automatic External Defibrillator (AED) and a unitary carrying case for use by medical personnel or emergency medical personnel. However, Kirchgeorg et al. fail to suggest providing an emergency medical kit with a medication included therein and further fail to suggest that an emergency medical kit be provided to a person susceptible to a heart attack, stroke or other attack of a vascular disease or that treatment be predetermined in accordance with the needs of the person or that the patient should carry out any self-administered treatment at all. Accordingly, Kirchgeorg et al. never teach, suggest or suggest any desirability for the specific limitations of claims 19, 21, 22 and 25, which each require providing an emergency medical kit including a medication for treating an attack of a vascular disease to a person with known susceptibility to an attack of a vascular disease.

Applicant submits that neither Zapol et al. or Kirchgeorg et al. alone, nor Zapol et al. and Kirchgeorg et al., in combination, teach or suggest the claimed combinations of rejected claims 19, 21 and 25. Specifically, claims 19, 21 and 25 require providing the patient with a portable emergency medical kit and teaching the patient how to recognize predefined symptoms of the serious attack and how to carry out the treatment upon the onset of symptoms and these limitations are not taught or suggested by any of the prior art of record. It is submitted that the Examiner has failed to establish a *prima facie* case of obviousness with respect to rejected claims 19, 21 and 25. Accordingly, reconsideration

and withdrawal of the rejection of claims 19, 21 and 25 under 35 U.S.C. 103 (a) as being unpatentable over Zapol et al. in view of Kirchgeorg et al. is hereby requested.

Regarding rejected claim 22, neither Zapol et al. nor Kirchgeorg et al. includes any suggestion to make the claimed combination, specifically to provide a person susceptible to a serious attack of a vascular disease with a breathable oxygen delivery system and a medication for use in response to symptoms of the serious attack. Moreover, neither of the references suggests that the steps of claim 22 would have any reasonable expectation of success. It is submitted that the Examiner has failed to establish a *prima facie* case of obviousness with respect to claim 22. Accordingly, reconsideration and withdrawal of the rejection of claim 22 under 35 U.S.C. 103 (a) as being unpatentable over Zapol et al. in view of Kirchgeorg et al. is hereby requested

Applicant submits that the claims pending herein set out a combination of features that is not taught or suggested by any of the prior art of record. Moreover, it is submitted that the prior art of record fails to suggest any desirability of the claimed combination of features nor does the prior art of record offer any reasonable expectation that the claimed combination of features would be successful at preventing death or permanent tissue damage in a patient suffering from a serious attack of a vascular disease, which restricts blood circulation. The invention claimed herein addresses the need for a simple low cost portable emergency medical kit that is given or prescribed to the user, that is customized to the particular needs of the user, and that could save the life or reduce the risk of permanent tissue damage of a victim of a serious attack of a vascular disease such as a heart attack, stroke or other life threatening condition caused by vascular disease or trauma in a person that has a known susceptibility to such an attack. An emergency medical kit including breathable oxygen and a medication or combination of medications for administering treatment and especially for self administering treatment for a serious attack of a vascular disease during the period between the onset of symptoms and the arrival of a trained medical professional can save a persons life, yet is nowhere suggested in the cited prior art nor is there a suggestion that such a medical kit would be desirable.

Accordingly, Applicant hereby submits that each of the pending claims is in condition for allowance because the elements and limitations set forth in the claims are not anticipated or suggested by any of the prior art of record whether the prior art of record is taken alone, in combination or in combination with the knowledge of one having ordinary skill in the art at the time the invention was made. It is further submitted that the entire teaching of the claimed combination of features of the present invention is provided by the Applicant in the specification as filed.

If the Examiner feels that any further discussion of the invention would be helpful, perhaps in the form of an Examiner's Amendment, applicant's representative is available by Tel. (781) 541-6579 or by Fax: (781) 541-6747 and earnestly solicits such discussion.

Respectively submitted,

Applicants

Edward L Kelley

By: Edward L. Kelley Date: August 6, 2003
Agent for Applicant
Reg. No. 41,112
4 Militia Drive
Lexington, MA 02421